

REMARKS

Please reconsider the application in view of the above amendments and the following remarks.

Disposition of Claims

Claims 1-55 are pending in this application. Claims 3-20, 24-39 and 43-55 are withdrawn from consideration. Claims 1, 21 and 40 are independent. The remaining claims depend either directly, or indirectly, from claims 1, 21 and 40.

Claims 1, 21 and 40 have been amended in this reply to include the limitations discussed during the telephone conference of July 8, 2004. These limitations include the clarification of the location of the wedge, disclaiming the area under the center of a first metatarsal, the clarification of the concept of deflection of the proximal phalanx, and the clarification of the direction of inclination. The amendments also clarify that the wedge will be properly sized and placed, so that there is no ambiguity as to the location or position of the wedge, regardless of foot size. No new matter has been added by way of these amendments. Support for these amendments may be found at least in the original claims and in Figures 15 and 16 of the application as filed.

Furthermore, in consideration of the Examiner's assertions that functional claim language and statements of intended use do not make an otherwise unpatentable claim patentable, Applicant submits that the language introduced into claims 1 and 21 by way of these amendments imparts structural limitations to the claimed embodiments. Such language, showing the interrelationship of parts of an invention, has been upheld by the courts to be acceptable for differentiating a claimed invention over the prior art. *See e.g., In re Venezia*, 530 F.2d 956 (C.C.P.A. 1976) (language such as "adapted to be positioned," "adapted to be affixed," and "adapted to be fitted over" is acceptable when it precisely defines present structural attributes of interrelated parts); and, *Dennison Mfg. Co. v. Ben*

Clements and Sons, Inc., 467 F.Supp. 391 (S.D.N.Y. 1979) (“adapted to” language is acceptable when it excludes a particular interpretation from the scope of the claims, when read in light of the specification and drawings).

With respect to the negative limitations introduced into claims 1, 21, and 40, as stated in the M.P.E.P. at § 2173.05(i), as long as the claim complies with 35 U.S.C. § 112, there is nothing inherently ambiguous or uncertain about a negative limitation. Accordingly, the limitation that the wedge will not extend under a first metatarsal is believed by the Applicant to be proper, and to clearly differentiate the claimed embodiments over the cited prior art.

Examiner Interview

A telephone conference was held on July 8, 2004, between the Applicant, Applicant’s attorney, and Examiner Mohandesi. During the interview, differences between the instant application and the prior art were discussed. The Examiner indicated that further clarification to the claims was required, specifically with respect to the length of the claimed apparatus and the direction of inclination provided by the claimed apparatus. In light of these discussions, the instant claims have been amended accordingly, and Applicant believes the application is now in condition for allowance.

Rejections under 35 U.S.C § 103

Claims 1-2 and 40-42 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 6,092,314, issued to Rothbart (“Rothbart”). Claims 1 and 40 have been amended in this reply to clarify the location and configuration of the claimed embodiments. To the extent that this rejection may still apply to the amended claims, it is respectfully traversed.

Amended claim 1 recites an orthopedic appliance comprising a wedge

adapted to be placed beneath a toe in such fashion that it *will not extend under the center of a first metatarsal* (shown at 36 in annotated Figure 6 of Rothbart, below), and having a first upper surface disposed between an apex and a first end, and a second upper surface disposed between an apex and a second end, wherein the first upper surface is disposed at an angle of inclination relative to the lower planar surface in a *proximal to distal direction* so that the proximal phalanx (46) is deflected upwardly relative to the first metatarsal (36). In contrast to such a device, Rothbart discloses a forefoot support surface having a back edge positioned **posterior to the first metatarsal (36) but anterior to a plantar surface of the calcaneus (27)** (Col. 6, ll. 30-32).

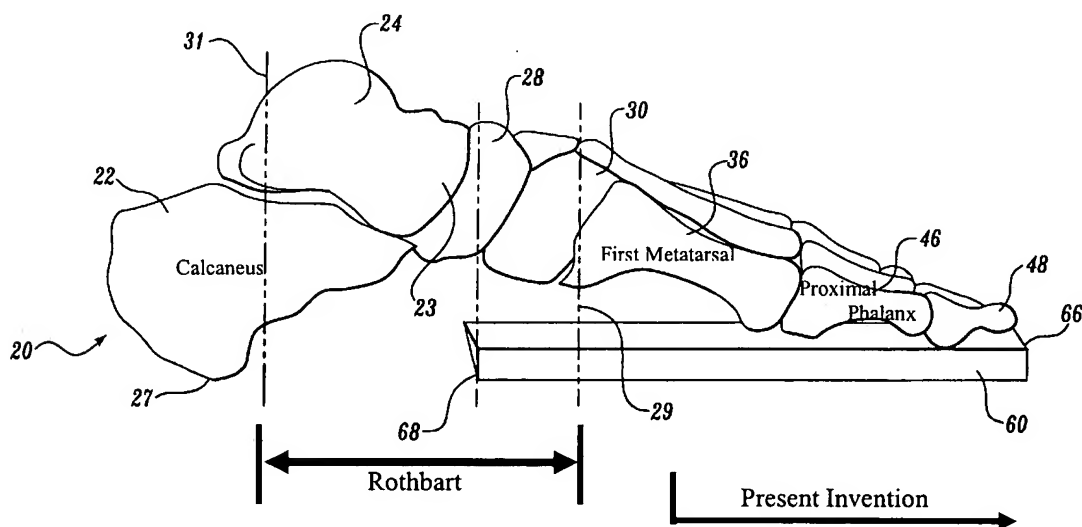


Figure 6 of Rothbart (annotated)

As shown in Figure 6, and described at Col. 6, ll. 33-37, “the back edge 68 may line in, along or between a reference line 29 at the posterior end of the first metatarsal 36 to a reference line 31 at the anterior end of the plantar surface 27 of the calcaneus 22.” Thus the Rothbart device will always extend beneath the center of a first metatarsal. Furthermore, the forefoot support device according to Rothbart is configured to cause an angle of inclination *across* the medial column of the foot (i.e., in the transverse plane), and not in a proximal to distal direction (i.e., in the sagittal plane), as required by the instant invention. Figure 4 of Rothbart (at right) demonstrates “Rothbart’s Foot Structure.” wherein the hallux (first metatarsal) 48 is elevated and twisted. Rothbart’s invention is “directed to a foot support system that effectively builds the ground up to the medial column of a foot exhibiting Rothbart’s Foot Structure, thereby supporting the foot in its anatomical position so that the foot does not inwardly collapse...” (Col. 6, ll. 8-12).

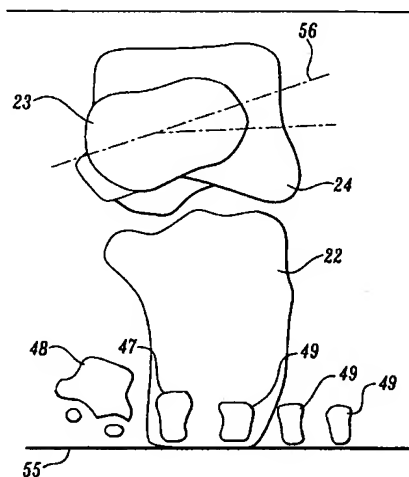


Figure 4 of Rothbart

In contrast to Rothbart, the invention of claim 1 raises a proximal phalanx with respect to a first metatarsal, thereby advantageously facilitating plantarflexion of the first metatarsal through the late midstance and propulsive phases of gait (Paragraph 66 of the current application). The invention according to Rothbart instead elevates the first metatarsal and does not facilitate the biomechanical

action (described above) that is an advantage of the instant invention. Therefore, withdrawal of this rejection with respect to claim 1, as well as claim 2 which depends from claim 1, is respectfully requested.

Claim 40, as amended, recites a method for improving stability of the foot comprising fitting and placing a wedge such that it is located *forward of, and not extending under, the center of a first metatarsal*, and *deflecting a proximal phalanx upwardly in a proximal to distal direction, relative to a first metatarsal*.

In contrast, Rothbart discloses a forefoot support system **extending from the hallux to proximal to (past) the first metatarsal head** (Col. 6, ll. 24-25, 33-37 and Fig. 6). Furthermore, the forefoot support system according to Rothbart elevates the medial column of the forefoot relative to the remainder of the forefoot (i.e. the angle of inclination according to Rothbart is across the foot, i.e., in the transverse plane) as indicated by the fact that the Rothbart device “does not significantly elevate the phalanges 47 of the second toe” (Col. 6, ll. 41-42) while supporting the medial column of the forefoot in an elevated position relative to the remainder of the forefoot (Col. 6, ll. 57-58). Thus, Rothbart supports the entire medial column relative to the rest of the forefoot (i.e. inclination is across the foot – see Figure 6 above), in contrast to the support method of claim 40 that elevates a proximal phalanx relative to a first metatarsal (i.e. inclination is along the foot).

Nothing in the specification or the figures of Rothbart suggests that Rothbart “elevates a proximal phalanx to a predetermined angle of inclination

using the wedge, relative to a first metatarsal” (Office Action at p. 3). With respect to the annotated Figure 6 that accompanies the Office Action, Applicant respectfully disagrees with the Examiner’s interpretation of the fact that an arbitrarily selected point on the upper surface of one bone being higher than an arbitrarily selected point on the bottom surface of an adjacent bone evidences any type of inclination.

In view of these distinctions claim 40, and claims 41-42 which depend from claim 40, are patentable over Rothbart. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 21-23 stand rejected under 35 U.S.C. § 103 as being obvious over Rothbart. To the extent that this rejection may still apply to the amended claims, it is respectfully traversed.

Claim 21 recites an apparatus for orthopedic treatment comprising a support *adapted to deflect a proximal phalanx upwardly in a proximal to distal direction relative to a first metatarsal*. When properly sized and placed, *this support will lie forward of, and will not extend beneath, the center of the first metatarsal*. As previously discussed with regard to claim 40, above, Rothbart discloses a forefoot support system extending from the hallux to proximal to (past) the first metatarsal head (See Col. 6, ll. 24-25, 33-37 and Fig. 6). Such a configuration clearly will extend beneath the center of a first metatarsal.

Furthermore, Rothbart's forefoot support system elevates the medial column of the forefoot relative to the remainder of the forefoot. Thus, the biomechanical basis of the Rothbart device is contrary to that of the current invention, which advantageously allows for retrograde plantarflexion of the first metatarsal head.

Applicant fails to discern the Examiner's basis for the statement that the Rothbart device "maintains the proximal phalanx at an angle of inclination... relative to a first metatarsal" (Office Action at p. 3). Although the Examiner references Col. 6, ll. 66-67, Col. 7, ll. 1-19, and Fig. 10, none of these contain a relevant disclosure. Col. 6, ll. 66-67 discusses a **downward slope** of the upper surface of the foot support system. Col. 7, ll. 1-19 discuss various configurations of the foot support system, none of which relate to an **inclination** of a proximal phalanx relative to a first metatarsal in a proximal to distal direction. Finally, Fig. 10 is a **cross-section** of the foot support system (see Col. 3, ll. 5-8) and therefore cannot possibly disclose an angle of inclination *in a proximal to distal direction*. In fact, there is no suggestion in the specification or figures of Rothbart of a device which deflects the proximal phalanx upwardly at an angle of *inclination in the proximal to distal direction, relative to a first metatarsal*. Instead, Rothbart supports the entire medial column relative to the rest of the forefoot. For at least these reasons, claim 21 is patentable over Rothbart. Claims 22-23, which depend from claim 21, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

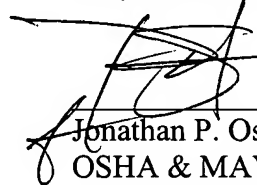
Conclusion

Applicants believe this reply to be fully responsive to all outstanding issues and place this application in condition for allowance. If this belief is incorrect, or other issues arise, do not hesitate to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 09166.002002).

Date: _____

8/5/04

Respectfully submitted,

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